REMARKS

The second Office Action mailed on March 19, 2003 has been carefully considered and the Examiner's remarks are appreciated. Claims 1-19 were originally in the application, and are presented for examination, with support for the amendments found in the Specification, Claims, and Drawings. In response to that Office Action, Applicants respectfully request reconsideration in view of the above amendments and the following remarks.

Brief Discussion of the Present Invention

Applicants' invention is a field-deployable SPME kit having all necessary equipment for performing SPME collection, isolation, and concentration, and including a plurality of hermetically sealed transport tubes each securely retaining and transporting a SPME fiber syringe assembly. Furthermore, the transport tubes are all carried within a common casing, and function to prevent cross-contamination between SPME fiber syringe assemblies which may be possible due to external contamination of any one of the SPME fiber syringe assemblies.

Discussion of the Office Action

In the second Office Action, the Examiner provisionally rejected claims 1-19 under obviousness-type double patenting. And the Examiner rejected claims 1-19 under 35 U.S.C. §103(a).

Discussion of Rejections Under 35 USC § 103

The Examiner rejected claims 1-19 under 35 U.S.C §103(a) as being unpatentable over "Optimization of the SPME Device Design for Field Applications" by Pawliszyn et al or U.S. Pat. No. 5,693,228 to Koehler et al., in view of U.S. Pat. No. 5,672,883 to Reich, and further in

view of U.S. Pat. No. 6,042,787 to Whitcher et al. or U.S. Pat. No. 4,303,610 to Sardisco et al. It is respectfully submitted, however, that the Examiner's 103 based rejections are inappropriate for failure to make a prima facie case of obviousness, in view of MPEP §2143.03 as follows in part:

> *"To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art."*

In support of his 103 based rejections the Examiner stated that, *"the cited art teaches SPME fibers within syringe housings and septums"* (emphasis added), presumably in reference to Pawliszyn and Koehler. The Examiner also stated that, *"Reich teaches means to protect a syringe assembly during transport"* (emphasis added) and that it would have been obvious to modify Pawliszyn or Koehler, in view of Reich, to *"provide a protective container having an interconnecting top and bottom portion to gain the advantages of preventing premature discharge of the syringe's contents and provides easy/safe disposal of contaminated syringes."*

It is respectfully submitted, however, that no teaching, suggestion, or motivation is found in Pawliszyn, Koehler, or Reich to seal and protect a SPME fiber syringe assembly using a sealed transport tube, as required in independent claims 1, 11, 13, 15, and 16. It is readily appreciated, that the SPME fiber syringe assemblies, i.e. SPME field samplers, described in Pawliszyn or Koehler are structurally and functionally distinct from the common "syringe assembly" described in Reich. When radiological material is contained in the syringe assembly of Reich, the syringe assembly has no capability, built-in or otherwise, for sealing and/or radiation shielding the radiological material. The combination radiological pig and sharps container of the Reich patent is therefore utilized to address this problem by providing *"some degree of radiation shielding,"* (column 1, lines 48-51) as well as protection against *"the risk of injury posed by the sharp hypodermic needles"* (column 1, lines 51-58). In contrast, and as

correctly noted by the Examiner above, SPME field syringe assemblies such as those described in Pawliszyn or Koehler are already provided with sealing caps or septums, built-in or otherwise, at or near the tip of the active SPME fiber, for sealing the fiber when retracted for storage or transport. As mentioned in Pawliszyn, this is because *"The most important requirement for a reliable field sampler is the minimization of sample losses from the SPME fiber and of fiber contamination during transport and storage."* Thus, whereas the syringe assemblies in Reich require a separate container to ensure against radiation leakage and contamination, SPME collector/field samplers are already provided with means for fiber sealing and sample protection. Consequently, there is no teaching or suggestion to combine either Pawliszyn or Koehler with Reich to further seal and store an already sealed SPME syringe assembly in a separate transport tube. Nor is there any motivation taught or suggested to do so.

Also in support of his 103 based rejections of claims 1-19, the Examiner stated, *"The art is silent to the assembly of a plurality of SPME fiber syringe assemble in a kit,"* but that according to St. Regis Paper Co. v. Bemins Co., Inc, *"duplication of parts has no significance unless a new and unexpected result is achieved. It is advantageous to duplicated parts in a test kit so that multiple tests may be performed from the same packaging which avoids waste and makes the testing more economical."*

Contrary to the Examiner's view, however, duplication of the transport containers of the present invention is not simply to allow the conduction of multiple tests for economy and efficiency reasons. As mentioned above in the Brief Discussion of the Present Invention, the plurality of hermetically sealed transport tubes are all carried within a common casing, and function to prevent cross-contamination between SPME fiber syringe assemblies which may be caused by exterior contamination of any one of the syringe assemblies. This is an important goal

of the present invention for which there is no teaching or suggestion in any of the cited references. While the prior art teaches sealably storing SPME fibers within syringe housings and septums to prevent contamination of the fiber, it does not address the possible contamination of the SPME syringe housing itself during sampling, and the possible communication of such contaminants to other syringe assemblies and fibers.

In order to clarify this distinction from the cited references, Applicants have amended independent claims 1, 11, 13, 15, and 16, as well as dependent claim 2 to incorporate the functionality of the transport tubes in preventing cross contamination. For example, amended claim 1 includes the language *"each transport tube for securely retaining a solid phase microextraction (SPME) fiber syringe assembly and preventing cross-contamination with another SPME fiber syringe assembly retained in another transport tube when carried together in said casing"* (emphasis added). Claims 2, 11, 13, 15, and 16 include similar terminology that also clarifies this distinction.

The Examiner also stated that Whitcher and Sardisco *"teach test kits supplying all of the necessary items as well as instructions for use in a carrying case. The advantages of such a test kit is they supply all of the necessaries to perform the test and obviate the problem of trying to assemble the components in a hasty fashion possibly missing essential elements. Kits are also advantageous because they are commercially expedient."* On this point, the Examiner's statements seem to suggest that any type of kit, which supplies all of the necessary items as well as instructions for use in a carrying case, would be obvious in light of Whitcher or Sardisco, irrespective of the particular functionalities provided by the kit's component parts. On the contrary, MPEP §2143.03 requires an examination of all the claim limitations in a claim. In the present invention, the claims specify the particular structures and operations of each of the tools

provided in the kit, for performing SPME sample collection, and providing safe transport of a SPME collection/sampling device from the field. For example, and as previously discussed, the kit of the present invention includes a plurality of transport tubes for the specific purpose of safely retaining a SPME fiber syringe assembly during transport, and preventing cross-contamination with another SPME fiber syringe assembly retained in another transport tube. In contrast, Sardisco discloses a test kit for field analysis of plat tissue magnesium and calcium, and Whitcher discloses a chemical test kit for testing the condition of water. Both the Whitcher and Sardisco references represent non-analogous art which do not address the same issues and operational concerns/parameters presented in the particular field of the present invention, and therefore do not provide, teach, or suggest the use of the same or similar kit components and equipment.

Additionally, and with respect to the 103 based rejections of independent claim 16 and dependent claims 2 and 9, the cited references do not teach or suggest the use of a septum on each of the transport tubes, for sampling within the transport tube in order to determine contamination. While the Examiner is correct in stating that, *"the cited art teaches SPME fibers within syringe housings and septums,"* there is no teaching or suggestion to incorporate a septum with the transport container of Reich to perform the same or similar function. While the prior art teaches the use of septums to seal SPME fibers tucked or retracted away for storage or transport, it does not teach or suggest providing a pierceable septum for sampling the inner volume within such supplemental transport tube/container to detect if external contamination of the SPME sampler itself has occurred. As previously discussed, the present invention enables the prevention of cross-contamination, and the septum is used to check against such external contamination of the SPME fiber syringe assembly. In this manner, the function of the septum in the present invention is fundamentally different from that described in the prior art.

With respect to claims 3-10, 12, 14, and 17-19, it is respectfully submitted that the 103 based rejections are also moot in view of the aforementioned discussion, as well as being dependent on now allowable independent and/or base claims.

Discussion of the Obviousness-type Double Patenting Rejection

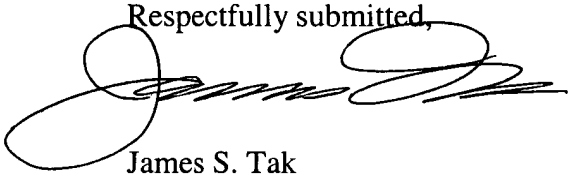
The Examiner provisionally rejected claims 1-19 under the judicially created doctrine of obviousness-type double patenting, as being unpatentable over claims 1-19 of co-pending Application No. 10/126,792. The provisional rejection is repeated from the first Office Action of (date), without responding to Applicants' arguments. In particular, the Examiner stated that *"although the conflicting claims are not identical, they are not patentably distinct from each other because both are directed to a SPME device"* (emphasis added). It is respectfully submitted, however, that the claims of the present invention are in fact patentably distinct from the above-referenced co-pending Application. As discussed above, the present invention claims a kit having a novel and unobvious combination of kit components which operate to retain a SPME fiber syringe assembly while preventing cross-contamination with another SPME fiber syringe assembly retained in another transport tube. Thus, the obviousness rejection is inappropriate because the claimed subject matter of the copending application would NOT have rendered obvious the invention as defined by the present claims under consideration at the time the invention was made. The Examiner's broad contention that the claims are not patentably distinct from each other "because both are directed to a SPME device" would seem to permit only one patent in the field of SPME devices, which is clearly not the intent of this judicially created doctrine.

Summary

Having amended the claims and/or traversed Examiner's arguments as discussed above, Applicant respectfully submits that claims 1-19 are in condition for allowance. Applicants respectfully request allowance of claims 1-19.

In the event that the Examiner finds any remaining impediment to the prompt allowance of these claims that could be clarified with a telephone conference, he is respectfully requested to initiate the same with the undersigned at (925) 422-7274.

Respectfully submitted,



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